Comments in Opposition to
Project ID No. M-8498-10
Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System
da Vinci S Surgical System

Comments Submitted by FirstHealth of the Carolinas.

Pursuant to NCGS § 131E-185, FirstHealth of the Carolinas (FirstHealth) submits these comments in opposition to the CON Application filed by Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System (CFVHS) to obtain a da Vinci S Surgical System.

CFVHS's Application cannot be approved for the following key reasons:

- The applicant made a fatal math error in its volume projections.
- The applicant fails to reasonably substantiate its volume projections.
- The Application's pro formas overstate revenues and misstate expenses, failing to demonstrate the financial feasibility of the project.

These and other reasons why the Application cannot be approved are discussed in detail on the following pages.

While CFVHS asserts that *"This project only requires CON approval because the cost of the equipment exceeds $750,000. No other aspect of this project is reviewable"* (Application at 35), the CON Section must nonetheless perform a thorough analysis of this project. Cost control is a substantial purpose of the CON Law. NCGS § 131E-175.

I. The Applicant Made a Fatal Math Error in Its Volume Projections, Rendering the Application Nonconforming With Criteria 1, 3, and 5.

CFVHS proposes to obtain a da Vinci S 4-Arm, HD Vision Surgical System, for a capital expenditure of $2,353,560. The da Vinci system is a "robotic" surgical system that permits a specially trained surgeon to sit at a control console, and direct the operation of robotic surgical arms and instruments that are inserted through small incisions in a patient's body, with high-definition monitors providing the surgeon a three dimensional, magnified view of the surgical field.

In attempting to demonstrate the need for its project, CFVHS states that:

> *Future surgical volume for the da Vinci Surgical Program was determined based upon two components. The first component assumes that a certain percentage of existing surgical cases at CFVHS are clinically appropriate for the da Vinci Surgical system and will transition to the da Vinci Surgical system over the next three years. The second component assumes that a certain percentage of the surgical volume that is clinically appropriate for robotic surgery which is leaving the Service Area currently to seek robotic surgery or conventional surgery will instead choose to receive robotic surgery as CFVHS.*

Application at 47.

In the second component of its volume projection, CFVHS thus asserts that it will "recapture" a certain volume of service area residents/patients who currently leave the service area in order to have surgeries elsewhere. CFVHS calls this the "Incremental Volume" component of its volume projections. CFVHS's projected Incremental Volume calculations are on pages 54-59 of its Application, concluding that in Project Year 3, these recaptured patients will comprise 165 of 568, or 29%, of the project's total volume. *Id.* at 59. Based on these projections, CFVHS asserts that the project will operate at a loss for the first two years, but will achieve an operating profit in Year 3. *Id.* at 104.

CFVHS's calculations regarding its Incremental Volume repeatedly contain a fundamental error, however, that cause the projected Incremental Volume to be exactly *double* what it should be. On page 54, in "Step 7" of its calculations, CFVHS explains that it *"reviewed Thompson inpatient and outpatient surgical cases performed over the last <u>two</u> federal fiscal years (FY) on residents of the da Vinci Surgery Program Service Area . . ."* (emphasis added). A chart showing the October 2007 – September 2009 volume is then provided on Application page 55.

CFVHS next identifies, in "Step 8" of its calculations, certain percentages of procedures that it asserts are clinically appropriate to perform on the da Vinci system *Id.* at 55. In "Step 9," CFVHS then identifies certain percentages of clinically appropriate cases that it asserts will be recaptured if a da Vinci is acquired (essentially a percent market shift). *Id.* at 56. (The problems inherent in these two calculations are addressed in Section II of these comments.)

CFVHS's fundamental error occurs next: On page 57, CFVHS provides a table that calculates, for 2009, the number of "lost cases" that it expects would be recaptured by the project (a total of 152). The problem lies in that CFVHS's starting data – on page 55 – is <u>two</u> years' volume totals, not one. As a result, the 152 cases that CFVHS expects to recapture should instead be no more than <u>76</u> (152 / 2 = 76).

The error is confirmed as follows, using inpatient urologic cases as an example (the same error exists, however, in each category of inpatient and outpatient Incremental Volume cases): The *two-year* table at the top of page 55 identifies 54 inpatient, primary service area urologic cases, and 155 inpatient, secondary service area cases, which are "lost" from the service area (i.e., have surgery outside the service area). The table at the bottom of page 55 then asserts that 50% of those lost urologic case would be appropriate for da Vinci surgery. Therefore, *for two years' volume*, that would be 27 urologic da Vinci surgery cases from the primary service area, and 77.5 urologic da Vinci surgery cases from the secondary service area.

In the table on page 56, CFVHS asserts that 50% of the lost, appropriate urologic cases from the primary service area, and 25% from the secondary service area, would be recaptured if CFVHS acquires a da Vinci. For the *two years'* data, this means that (27 x 0.5 = 13.5 =) 14 urologic cases from the primary service area, and (77.5 x 0.25 = 19.3 =) 19 urologic cases from the secondary service area, could be recaptured *over two years* if CFVHS acquires a da Vinci.

CFVHS then transfers the *two year* figures to the 2009 *one year* chart on page 57 (14 + 19 = 33; upper right row), and asserts that CFVHS lost these cases *in one year* for lack of a da Vinci. Using annual population growth rates, CFVHS then grows these lost cases (now mis-identified as one-year data) into and over the first 3 years of the project, showing 35 urologic cases in years 1-2, and 36 in year 3. So, annual growth rates have been misapplied to two years worth of cases. Application at 58, 59.

This error, which substitutes two years' data as the starting point for one years' volume projection, is repeated for each surgery type for all of the Incremental Volume cases projected on Application pages 54-59. The result, even if you assume that CFVHS's calculations and projections are otherwise flawless (which they are not, as discussed below), is that the Incremental Volumes stated on page 59 of the Application (which comprise 29% of the Total Projected Volume in Year 3), along with the resulting components of the applicant's revenue projections, are exactly double what they should be.

These errors cause the applicant's volume projections to be overstated, erroneous and unreliable, and the applicant thus fails to reasonably demonstrate the need for its project. Because the volume projections form a substantial basis for CFVHS's financial projections, the Application also fails to reasonably demonstrate the financial feasibility of its proposal. Given the error in the volume projections, it is impossible to demonstrate, from the information provided, that the project will be financially feasible at any point.

The calculation error and all the resulting miscalculations cannot now (after the CON filing date) be corrected or changed by CFVHS, as that would be an impermissible amendment to the Application. 10A NCAC 14C.0204.

The Application must therefore be found nonconforming with Criteria 1, 3, and 5.

II. The Applicant Fails to Reasonably Substantiate Its Volume Projections, Rendering the Application Nonconforming With Criteria 1, 3, 5, and 13(c).

Criterion 3 states that:

> *The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.*

NCGS § 131E-183(a)(3).

Because of fundamental flaws in the volume projections, however, CFVHS has failed to both identify the population to be served by the project, as well as the need such population has for the services proposed.

A. The Secondary Service Area Has No Need for the Project.

On page 26 of its Application, CFVHS identifies a six-county service area consisting of Cumberland County as the primary service area, and the adjacent counties of Bladen, Harnett, Hoke, Robeson, and Sampson as the secondary service area. Throughout its Application (e.g., pp. 47, 80), CFVHS emphasizes the importance of providing a da Vinci system to the residents of the entire service area. The Application's volume and financial projections are based upon patients drawn from all six counties. What CFVHS does not discuss, however, and a substantial flaw in its reasoning, is that of the five secondary service area counties, *three* of those counties (60%) are *already* adjacent to counties in which a da Vinci system is located. CFVHS does not address at all, however, why it is reasonable that these persons will drive to Cumberland County, when a da Vinci system is already established in another county adjacent to them.

Application page 18 lists 30 North Carolina hospitals already providing da Vinci services. Of the five counties in the secondary service area, Hoke, Harnett, and Sampson are adjacent to another county that already has a da Vinci system. Hoke County is adjacent to Moore County, where FirstHealth Moore Regional Hospital (FMRH) has a da Vinci Surgical system. Most of Hoke County, including Raeford, is closer to FMRH than to Cape Fear Valley Medical Center (CFVMC), and existing surgical relationships are established. Similarly, Harnett County (including its populous northern portion) is adjacent to Wake County, where there are several da Vinci systems in operation at Wake Med, Duke Raleigh and Rex Hospitals. Sampson County is adjacent to Wayne County, where Wayne Memorial Hospital already has a da Vinci system (the Sampson County seat of Clinton is approximately equidistant between Wayne Memorial and CFVMC).

Therefore, 60% of the counties in the secondary service area are already adjacent to a county with da Vinci services, and have reasonable access to such services. One of the major intended benefits of da Vinci surgeries are shorter hospital stays. *See* Application at, e.g., pp. 42, 43, 45. CFVHS assumes that residents of the secondary service area counties will come to CFVMC for da Vinci services, but provides no information to explain why someone in, for example, Harnett County (where a substantial portion of the population is in the northern part of the county and already oriented toward Raleigh), would prefer to drive to CFVMC in Fayetteville, when, as noted above, there are at least three da Vinci systems operational in Wake County.

An applicant is required to identify and explain all of the assumptions underlying its volume projections, and since CFVHS has failed to do so, its projections of the number of residents of the counties adjacent to Cumberland that will travel to CFVMC for da Vinci services is unsupported, and therefore unreliable and unreasonable.

In addition, Bladen County, while not adjacent to a county having a da Vinci system, is situated such that much of that county and its population are as close to the existing da Vinci system at New Hanover Regional Medical Center (NHRMC) in Wilmington as it would be to a da Vinci at CFVMC. While Bladen County Hospital is affiliated with CFVHS, that does not mean that Bladen County residents will necessarily choose CFVMC over a more convenient alternative. As examples, 12.7% (9 of 71) of Bladen County residents having gynecologic procedures in federal fiscal year 2009 were discharged from NHRMC, and 14.8% of Bladen County residents having nephrology/urology procedures (during that same period) were discharged from NHRMC.[2] Therefore, residents in four of the five secondary service area counties (80%) have existing options for da Vinci, and it is unreasonable to assume they will travel to CFVMC. Finally, Robeson County, where much of the population is already within reasonable distance of the da Vinci at FirstHealth Moore Regional Hospital, is also located within a reasonable distance of Carolinas Hospital Systems and its existing da Vinci system in nearby Florence, South Carolina.[3] So, each of the five counties in the secondary service area already has reasonable access to da Vinci services.

CFVHS has failed to reasonably demonstrate a need for the proposed services in most, if not all, of its secondary service area, and its projections are flawed thereby.

B. The Volume Projections Are Unreasonable.

As previously stated, CFVHS's assumptions regarding projected volume have two components: first, that some portion of the population already having surgeries at CFVMC will be appropriate for da Vinci surgeries, and second, that certain residents of the service area who are now going outside the service area for surgeries can be "recaptured" if a da Vinci is acquired (these are the Incremental Volume cases discussed in Section 1 above). Application at 47. The first component accounts for 71%, and the second component for 29%, of the Year 3 projected volume for the project. *Id.* at 59.

CFVHS is required to explain and justify all of its assumptions for its projected volume. In addition to the fatal math error regarding the Incremental Volume discussed in Section 1 above, however, CFVHS further failed to reasonably explain and justify either component of its volume projections.

1. The Fundamental Assumptions Are Unreasonable.

Regarding the first component of its volume projections, CFVHS fails to reasonably explain and justify its fundamental assumptions regarding which currently open or laparoscopic surgical procedures could, in the future, be performed on a da Vinci system. CFVHS states on page 48 that CFVHS and the da Vinci vendor identified procedures clinically appropriate for the da Vinci program. Other than general statements about *"extensive discussions"* with the vendor to determine which procedures could be performed, and a vague reference to determinations made by surgeons and others, *id.* at 49, CFVHS

[2] Thomson Reuters Market & Facility Inpatient Data: Inpatient NC (MS-DRG) 10/01/2008 - 09/30/2009.

[3] *See* the hospital locator at www.davincisurgery.com.

provides no information whatsoever to justify the fundamental assumptions regarding projected procedure types and volumes provided in its Application on pages 48-49.

On page 49 CFVHS projects that 50% of the urologic cases performed at the hospital are clinically appropriate for the da Vinci system, 50% of gynecologic cases, 25% of the cardiothoracic cases, and 25% of general surgery cases. Other than the very general statements described above, however, the applicant fails to describe its basis for projecting which surgical procedure types are appropriate to be performed on the da Vinci, as well as how it determined the percentages of such cases that it projects will be performed on the da Vinci (the chart on page 49). An applicant is required to provide all of the assumptions underlying its projections, and in this case, the applicant has failed to do so, resulting in projections of both procedures and volumes which are unsupported and therefore unreliable and unreasonable.

Given the projections' lack of support, it is just as likely that the percentage of, for example, urologic surgeries capable of being performed on a da Vinci system may be 37%, or 42%, or 54%, instead of the 50% asserted on page 49. In fact, the table on page 49 appears to be nothing more than a general estimate, since its four projections are only given as two 25% and two 50% figures. Further, the data tables cited as the source of the projections (at Exhibit 24) do *nothing* to support the percentages, but instead only repeat them without explanation.

The da Vinci system was first approved by the FDA in 2000, and is now in use at 930 or more hospitals. *Id.* at 17. One would expect that CFVHS would have used actual, experiential utilization data in making its projections. While the application vaguely refers to unnamed vendor representatives confirming that the estimates were "consistent" with the experience of other hospitals (Application at 28), the vendor representatives are not identified, no North Carolina or other hospitals are identified, and no time period is identified. CFVHS offers no evidence other than very general, nonspecific statements to support the very foundation of its volume projections. The volume percentages have no reasonable basis of support, resulting in unreliable and therefore unreasonable volume projections.

2. The Ramp-Up Assumptions are Unreasonable.

On page 53 of its Application, CFVHS states that its Year 1-3 volume projections *"reflect the necessary ramp-up time during which surgeons at CFVHS will train to use the da Vinci Surgical System and adapt their practice patterns to the availability of that new technology."*

On page 58, CFVHS identifies the ramp-up steps as being 30% in Year 1, 50% in Year 2, and 100% of the projected volume in Year 3. CFVHS provides absolutely no explanation or support, however, to show that the 30%, 50% and 100% steps are reasonable assumptions, and the numbers could just as easily be entirely different. CFVHS could just as easily have assumed ramp-up steps of 50%, 75% and 100%, or 20%, 66% and 100%. While actual data from other users should be available, none is offered, likely because it would show that the actual ramp-up time does not support the applicant's projections. The applicant's projections of volume are essentially arbitrary, and are unreliable and unreasonable.

3. The Incremental Volume is Unreasonable.

In addition to the errors described above, in projecting the Incremental Volume to be recaptured, CFVHS states that it reviewed not only cases performed on a da Vinci system (on service area residents, but outside the service area), but *also* cases that were performed by open surgery or laparoscopic procedures.

Application at 54. CFVHS has no way of determining, however, how many of those cases might have been surgically appropriate for a da Vinci procedure, and is therefore overstating the universe of cases to potentially recapture. It would have been more reasonable to use only those "lost" cases that were performed on a da Vinci system outside the service area, although even that statistic may not have led to a reasonable result, given the other flaws in the volume projections.

So, in addition to the fundamental math errors, CFVHS's volume projections suffer from lack of substantiation, rendering them unreasonable.

C. The Project Fails to Provide Equitable Access to Healthcare.

To conform to Criterion 1, the applicant must comply with all applicable State Medical Facilities Plan (SMFP) policies. NCGS § 131E-183(a)(1). Policy Gen-3 of the 2010 SMFP states, in relevant part, that:

> *A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.*

2010 SMFP at p. 48 (of online .pdf version).

Criterion 13 also provides in relevant part that

> *The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:*
>
> . . . .
>
> *c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services* . . . .

In the Application's Section 6, Accessibility, on page 85 at question 12, CFVHS identifies that Self-Pay/Indigent/Charity care accounted for 12.6% of the total utilization at the hospital in FY 2009. In question 13 (p. 86), CFVHS identifies that Self-Pay/Indigent/Charity cases accounted for 5.2% of inpatient services and 11.9% of outpatient services for the total case utilization at the hospital. The response to question 13 actually appears nonresponsive to the question, which instead asks that the information be provided for only each service component included in the proposed project, and not the "total case mix" that CFVHS provided. Similarly, question 14(a) on page 87 asks the applicant to provide projected volume for the entire facility for the second fiscal year following completion of the project. CFVHS's response, however,

indicates that it instead only provides the payor mix for the Incremental Volume associated with the da Vinci Surgical Program.

The data provided in response to questions 13 and 14, however nonresponsive, does raise a concern. If Self-Pay/Indigent/Charity care constitutes 12.6% of the total utilization at the hospital, and 5.2% of inpatient and 11.9% of outpatient total case utilization (the correlation between these numbers is not explained), yet only 2.6% of the projected Incremental Volume on the da Vinci system (p. 87), then it appears that something, or someone, plans to deny the Self-Pay/Indigent/Charity patients from having access to the da Vinci system. In fact, when comparing the question 13-14 charts on pages 86-87, the projected da Vinci patients appear to be far more heavily weighted toward private insurance providers. Managed care and Blue Cross payors constitute 56.2% of the projected payors for the da Vinci system in question 14, while only 19.3% of inpatient and 23.9% of outpatient payors in question 13. It therefore appears that the project is not intended to provide equitable access to health care. Neither the information provided on page 88, nor the information provided at Tab 13 of the Application, cure this concern. The project therefore fails to promote equitable access to healthcare, in violation of Policy Gen-3 and Criteria 1 and 13(c).

Therefore, in addition to the fundamental math error described in Section 1, the assumptions utilized in CFVHS's volume projections are unsupported and unreliable, and the project appears biased against patients with limited financial resources. The volume projections, along with the resulting financial projections, are unreasonable, and the Application must be found nonconforming with Criteria 1, 3, 5 and 13(c).

III. The Application's Pro Formas Overstate Revenues and Misstate Expenses, Failing to Demonstrate the Financial Feasibility of the Project.

Criterion 5 requires that *"Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service."* NCGS § 131E-183(a)(5).

As an initial matter, the applicant's erroneous and unreasonable volume projections, as described in Sections I and II above, serve as a substantial basis for its projections regarding the financial feasibility of the project, thereby rendering those financial projections likewise erroneous and unreasonable. While that alone is sufficient basis for the Agency to find the Application nonconforming with Criterion 5, that is not the only basis for doing so.

The applicant is required to provide all assumptions and describe the methodology used to develop the Balance Sheet (the Form A) provided in Section X of its Application. On page 102, CFVHS describes four assumptions, but fails to describe the methodology used to develop the Balance Sheet, and therefore fails to meet the stated requirement.

One of the stated assumptions on page 102 is that *"current operations of CFVHS will achieve operating income improvements of $1 million each year through projects."* CFVHS provides absolutely no information, however, to support that assumption. Likewise, CFVHS provides no basis to support its assumption that *"current Cape Fear Valley Health System balance sheet accounts remain relatively stable and consistent with current trends."* However, in May 2008 the CEO of CFVHS wrote the agency, saying that CFVHS was experiencing cash flow problems. (*See* the Appendix to these comments, at p.3, *"Financial Challenges"*.) Further, since there is no substantiation of the operating improvements of $1 million and no substantiation that this will or has translated into cash flow, the assumptions without supporting documentation cannot be relied upon.

At Tab 13 of the Application, the financial assumptions for the Forms B, C, D, and E are provided. In the Form C - Statement of Revenues and Expenses for Each Service Component, the applicant states *"Only projected incremental volumes have been utilized in the Proformas to justify the expense associated with acquiring the da Vinci Robotic Surgical System. These projections are reflected in Section II and II* [sic] *and are also outlined below."* As explained in the prior sections of these comments, however, because of a fundamental math error, the Incremental Volume projections are double what they should be, and are otherwise unreliable and unreasonable. As a result, the financial pro formas for the project are irreparably flawed. Note that the Form A, Form B, Form C, Form D, and the additional forms for inpatient and outpatient services are all based on the Incremental Volume that is demonstrably erroneous and unreliable.

In addition, the applicant must not only demonstrate that capital and operating funds are available for the project, such funds must also be committed to the project. The letter at Exhibit 3 from CFVHS CFO Sandra Williams, however, only states that CFVHS *"is positioned financially to fund the project cost of $2,353,560 through operations and/or accumulated cash reserves . . . ."* The letter does not, however, commit the necessary funds to the project, and is therefore nonconforming with Criterion 5. Furthermore, given that there is no substantiation of the $1 million of improvements to operating income, there is at least some unreliability associated with "positioned financially".

As previously stated, because of the fundamental math error and other flaws in the volume projections, it is impossible to demonstrate, from the information provided, that the project will be financially feasible in Year 3 or any other point. Nor can CFVHS now come back and attempt to correct the calculation error and other flaws, because doing so would be an amendment to the Application. 10A NCAC 14C.0204 (an applicant may not amend an Application). CFVHS has also failed to commit the necessary funds to the project.

The Application is therefore nonconforming with Criterion 5 and must be disapproved.

IV. The Application Fails to Demonstrate the Availability of Surgeons Capable of Performing the Projected Procedure Volumes, in Violation of Criterion 7.

Criterion 7 provides that *"The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided."* NCGS § 131E-183(a)(7).

In its Application, CFVHS explains the credentialing prerequisites for surgeons wishing to utilize the da Vinci equipment, including certain training, case observation, and proctored procedure requirements. *See* Application at p. 33 (item (b)) and Exhibit 28. CFVHS does not, however, address whether its credentialed physician staff, or operating room staff, will be sufficient in any year to perform surgeries on the da Vinci in quantities to match the volume projections.

This project is not simply adding another operating room, or another piece of familiar equipment. The da Vinci is a complex, highly specialized surgical tool, with substantial credentialing requirements. While CFVHS states on page 41 of the Application that "several" physicians are already trained on the da Vinci, the applicant does not identify those physicians, nor state that they are ready to be credentialed at CFVMC to use a da Vinci. Of the eleven physician letters of support at Exhibit 20, only <u>one</u> of the letters, from Dr. Christian deBeck, states that he is trained in robotic surgery. Dr. deBeck, however, is not listed on the "find a physician" website for CFVHS.[4] He instead currently appears on the staff of New Hanover Regional Medical Center, and appears to practice with Wilmington Health Associates, both in Wilmington.[5] In fact, the da Vinci "surgeon locator" website identifies no surgeons in the CFVMC zip code 28304; the closest surgeons instead appear to be at FirstHealth in Pinehurst.[6]

CFVHS also states that nine surgeons "have expressed interest" in utilizing the da Vinci system. Application at 93. According to the da Vinci vendor quote, surgeon training will be provided at $3,000 per physician, and proctoring at $3,000 per day. Exhibit 7, p. 9, §§ 8-9. These charges are separate from the acquisition cost of the robot. *See id.* at p. 3 §§ 6-7. CFVHS has only budgeted $18,487 for educational expenses in Year 1, however, which is *totally* inadequate to credential nine surgeons on a da Vinci. Application Tab 13, Form B (Other Direct Expenses).

Because CFVHS does not indicate how many trained and credentialed surgeons will be necessary to generate the projected procedure volumes, does not substantiate how many physicians are presently capable of being credentialed without further expense, and proposes inadequate funding to train the physicians who have reportedly expressed interest in utilizing the da Vinci, it is impossible for the Agency to determine that CFVHS will have the necessary health manpower resources for the provision of the proposed services. In fact, it appears that CFVHS will *not* have sufficient surgeons to meet its volume projections. The applicant has therefore failed to evidence the availability of physician resources necessary to provide the proposed services, in violation of Criterion 7.

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[4] *See* http://capefearvalley.photobooks.com/.

[5] *See* http://www.nhrmc.org/body.cfm?id=22; http://www.wilmingtonhealth.com/provider/debeck/christian/. A Google search attempting to connect Dr. deBeck with CFVMC revealed no apparent connections.

[6] *See* http://www.davincisurgery.com/surgeon-locator/. Note also that *none* of the four da Vinci surgeons listed in Pinehurst appear on the CFVMC physician website.

V. The Application Fails to Demonstrate That the Least Costly or Most Effective Alternative Has Been Proposed, in Violation of Criterion 4.

Criterion 4 requires that *"Where alternative methods of meeting the needs where the proposed project exists, the applicant shall demonstrate that the least costly or most effective alternative has been proposed."* NCGS § 131E-183(a)(4).

On page 61, the applicant is required to discuss the various alternatives that were considered in developing the proposed project, and the reasons the alternative chosen was the most effective alternative of those considered. CFVHS states that it *"briefly considered maintaining the status quo,"* but quickly dismisses that alternative, saying *"the status quo is not acceptable to administrators, surgeons, and patients of CFVHS."* CFVHS does not explain, however, what has changed in the past 10 years since FDA approval of the da Vinci system that makes the status quo no longer an effective alternative. For the 10 years that the da Vinci system has been in use, the status quo has not caused CFVHS to previously request a da Vinci, yet the applicant provides no rationale why now, 10 years later, it is suddenly no longer acceptable to administrators, surgeons, and patients to be without a da Vinci system.

In addition, CFVHS did not discuss any other possible alternatives, including partnering with another provider to obtain a da Vinci system, or leasing a da Vinci system. It would appear that either of those alternatives are reasonable and carry less financial burden and risk for the hospital, yet neither are even mentioned.

VI. The Application Does Not Comply With Criteria 6, 18a, and 14.

Criterion 6 provides that *"The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities."* NCGS § 131E-183(a)(6). Given that most, if not all, of the counties in the secondary service area already have reasonable access to a da Vinci system (*see* Section II.A above), CFVHS has not demonstrated that its proposal will not result in the unnecessary duplication of services, and the Application should be disapproved under Criterion 6.

Criterion 18a provides that *"The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of Applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its Application is for a service on which competition will not have a favorable impact."* NCGS § 131E-183(a)(18a).

CFVHS essentially ignores Criterion 18a. *See* Application at 80 (response to question 7). While there is no other da Vinci located inside the proposed service area, three of the five secondary service area counties are already adjacent to another county that contains a da Vinci system. *See* Section II.A above. CFVHS totally fails to discuss the effect its project may have on da Vinci services at FirstHealth Moore Regional Hospital, Wayne Memorial Hospital, Duke Raleigh Hospital, Rex Hospital, and WakeMed - all hospitals with da Vinci systems, which are in counties adjacent to the proposed service area. As CFVHS has ignored this issue entirely, its Application is nonconforming with Criterion 18a and should be disapproved.

Criterion 14 provides that *"The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable."* NCGS § 131E-183(a)(14). On Application page 69, CFVHS is required to describe how the proposed project relates to the clinical needs of health professional training programs in the area. CFVHS's response is essentially nonresponsive, and the Application should be found nonconforming with Criterion 14 and disapproved.

Conclusion

Given the fundamental math error which totally negates the reliability of both the volume projections and the resulting financial projections, and the other unreasonable assumptions and other problems identified in the Application by these comments, as well as for other reasons that the Agency may discover, CFVHS's CON Application to obtain a da Vinci Robotic Surgical System is fundamentally flawed and must be disapproved.

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FAMILY BIRTH CENTER
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HEALTHPLEX
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SLEEP CENTER

May 26, 2008

Ms. Lee Hoffman
Chief
Certificate of Need Section
Department of Health Service Regulation
2704 Mail Service Center
Raleigh NC 27699-2704

Received by the
CON Section

02 JUN 2008 11 : 27

RE: Acute Care Beds

Dear Ms. Hoffman:

Enclosed is the single page of information which we discussed briefly at the Acute Care Committee meeting on May 8, 2008.

History

First Acute Care Bed Request

On June 15, 2004, Cape Fear Valley Health System ("CFVHS") filed its certificate of need application for a construction and modernization project (the Valley Pavilion), Project M-7069-04, which included the transfer of 46 acute care beds from Highsmith Rainey Memorial Hospital ("HRMH") and the relocation of 50 acute care beds from Cape Fear Valley Medical Center ("CFVMC") to be situated in the new Valley Pavilion adjacent to the current CFVMC facility on Owen Drive. Only two patient floors were facility planned and financially planned in the project at that time.

That application was approved without conditions and pursuant to construction schedule will open on or about October 1 of this year.

The 2004 SMFP allocated 44 beds to Cumberland County with a file date of August 15, 2004. Cape Fear Valley Health System had been planning for three years for the Valley Pavilion and chose to file without waiting to address the 44-bed allocation in the fall of 2004.

Second Acute Care Bed Request

On August 16, 2004, CFVHS filed its application (project M-7093) to gain approval for the 44 beds allocated to Cumberland County in the 2004 SMFP. The application identified five areas for placement of the beds. Three of the beds were immediately put into service in the cardiac services intensive care area. During the implementation planning for the remaining 41 beds, cost

estimates provided by the architectural firm were exceeded due to Katrina weather impact, world oil and steel price increases and other related material prices. CFVHS filed its application (project M-7436-05) for a cost overrun for the 44 beds on August 15, 2005 and was approved to continue the development of the beds without conditions.

During the planning for the remaining 41 beds, the State Health Coordinating Council began to identify the need for another 25 acute care beds for Cumberland County in the 2006 SMFP.

Third Request for Acute Care Beds

On June 15, 2006, CFVHS filed its application (project M-7616-06) for the 25 acute care beds allocated in the 2006 SMFP. Plans for those beds included using vacated space for beds to be relocated to the Valley Pavilion. These beds were approved without conditions.

At this point, CFVHS management realized that enough beds had been allocated (44 -3 +25) without having to transfer the 46 beds from HRMH to the Valley Pavilion. Retaining the beds at HRMH supported the LTAC operations trending up.

Originally, CFVHS had planned to relocate 50 beds internally to the Pavilion. We now had 20 of those covered by the allocations (41+25 – 46 which was replacing the transfer from HRMH). Currently, the SHCC was planning another 22 beds to be allocated during the 2007 SMFP year.

Fourth Request for Acute Care Beds

On August 15, 2007, CFVHS filed its application for the 22 newly allocated acute care beds. These beds were approved without condition to occupy space vacated for the Pavilion. Spaces were ready for routine nursing activity with no facility work to be done.

Thus, at this point CFVHS needed only to transfer 2 acute care beds to comply with the new building requirements.

Our Request

As shown on the attached reconciliation page discussed on May 8, we have 91 new acute care beds allocated and approved. We lost six (6) beds due to construction (linking the Pavilion to the older part of CFVMS) resulting in 97 beds available and leaving two (2) beds to be transferred from HRMH to reconcile the project.

CFVHS has need to keep the 44 beds in tact at HRMH. We ask that you consider each of the following reasons to allow us to avoid transferring the 44 beds approved in the 2004 certificate of need application to transfer them to the new tower.

LTAC Need

We are currently running 82 percent occupancy in the 66 operational beds in our LTAC facility at HRMH and believe that continuing and growing need demonstrates that we keep 44 of the originally requested 46 beds intact (we have to transfer two to reconcile the project's total bed requirements).

Financial Challenges

CFVHS is experiencing some difficult cash flows with the implementation of the Pavilion and other operations. At some point, we intend to build onto the Pavilion with more routine bed space to modernize some of our other 391 acute care beds in the existing CFVMC. If additional allocations from the SMFP are not available as those plans mature, we would consider petitioning the state for the necessary transfer of beds.

Surrendering 44 Beds Will Create Acute Care Bed Need

With the current allocations as shown in the draft documents for the 2009 SMFP, should CFVHS surrender the 44 beds originally requested in 2004, the current working documents' excess of 32 beds would create a need of 12 acute care beds. We are happy with the three allocations previously approved and believe that we have met those allocations without having to change our existing licenses to comply with the 2004 facility plans with the exception of two beds at HRMH.

Existing Facility Constraints at CFVMC

Over the course of getting approval for the 91 new beds, each of our applications considered some implementation in the existing facility on Owen Drive. Due to the following reasons, we cannot implement some of those changes:

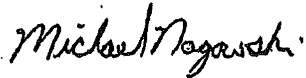
- Very inefficient to operate three (3) nursing units of 16, 15 and 10 beds.
- Cost prohibitive to renovate space in the oldest and only available building on campus.
- Doubtful the construction section would approve the space for all of the 41 beds.

Critical Mass of Acute Beds Difficult to Achieve

CFVHS petitioned in 2007 for 20 additional acute care beds due to the impeding BRAC realignment. Working under statewide population rates, we were unable to achieve additional acute care bed approval. We believe that surrendering one or two certificate of need applications to transfer the 44 beds discussed above will not only cripple our LTAC operations, we believe that the additional bed-need allocation will not be sufficient to regain our current operating position. As the SMFP has shown for near 10 years, CFVHS has experienced the highest percent utilization in its acute care beds in the state.

Please advise us of your questions. We respectfully request to make no changes to our licensure as having been approved with the exception of two (2) beds to account for the implementation of the Valley Pavilion.

Sincerely,



Michael Nagowski
President and Chief Executive Officer

Attachment

ATTACHMENT

Cape Fear Valley Health System

	Acute Beds With CONs			
	CFVMC	HRMH		
Licensed Beds	394	112		
Project M7069-04 (46 beds from Highsmith 50 beds from within to go into the Valley Pavilion)	46	-46		
	440	66		
Project M-7093-04 (44 beds with Project M-7436-05 cost overrun)	44 [1]			
Project M-76-16-05 (25 beds)	25 [1]			
Project M-7926-07 (22 beds)	22 [1]			
	531	66	=	597

	Actual Licensed Beds			
	CFVMC	HRMH		
Licensed beds	394	112		
CSICU beds from the 44 CON	3 [2]			
New Tower	96 [2]	-2		
Loss in connection -old tower	-6 [3]			
	487	110	=	597

Reconciliation:	
New CON approved allocations from SMFP	91 [1]
Used (96 +3)	-99 [2]
Lost in construction	6 [3]
Net to be transferred from HRMH	-2